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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/507,356 | 05/02/2005 | Christoffer Abrahamson | 1103326-0778 | 5661 |

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1155 AVENUE OF THE AMERICAS
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| EXAMINER | |
|---|---|
| ROSENBERGER, FREDERICK F | |
| **ART UNIT** | **PAPER NUMBER** |
| 2884 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/09/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/507,356 | ABRAHAMSON ET AL. | |
| | Examiner | Art Unit | |
| | Frederick F. Rosenberger | 2884 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) from the International Bureau for PCT/GB03/01052, which papers have been placed of record in the file. The International Preliminary Examination Report, dated 15 January 2004, for said application has also been communicated from the International Bureau and considered.

### *Drawings*

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **24** and **26** (Figure 1). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the setup for reflected radiation (per claim 3), transmitted with reflected radiation (per claim 4), and the setup with a blister pack (per claim 16) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 101*

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to a statutory category of invention (i.e. a process). However, the claims are directed to a judicial exception (i.e. a mathematical algorithm); as such, pursuant to the Interim Guidelines on Patent Eligible Subject Matter (MPEP 2106), the claims must have either physical transformation and/or a useful, concrete and tangible result. The claims fail to include transformation from one physical state to another. Although, the claims appear useful and concrete, there does not appear to be a tangible result claimed. Merely correlating signals to a parameter would not appear to be sufficient to constitute a tangible result, since the outcome of the correlating step has not been used in a disclosed practical application nor made available in such a manner that its usefulness in a disclosed practical application can be realized. As such, the subject matter of the claims is not patent eligible.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 5-15, 17-19, 22, 23, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sjoholm et al. (Journal article entitled "Analysis of gas dispersed in scattering media") in view of Mayer (European Patent Publication # 0110502-B1).

With regards to claim 1, Sjoholm et al. teach a method for analyzing the amount of free gas within a solid sample comprising:

Providing a sample before a diode laser irradiating source **DL** (Figure 1);

Irradiating the sample with NIR radiation in the range of 757nm to 761nm (page 17, first column);

Detecting the radiation either transmitted or reflected from the sample using a photomultiplier tube (Figure 1; page 16 column 2 through page 17 column 1);

Generating signals corresponding to the amount of free gas in the sample (abstract; page 17, second column); and

Correlating the signal to a measure of the diffusivity of the gas through the solid sample as a function of time (Figure 3; page 18, first column).

Sjoholm et al. do not specifically discuss application of the method to the detection of free gas in a pharmaceutical. However, Mayer teaches that the physical properties of a pharmaceutical depends upon the gas content of the pharmaceutical (see page 2, lines 49-65).

Thus, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to provide the method of Sjoholm et al. to a pharmaceutical so as to enable a quick non-destructive testing methodology based on detection of the free gas in a pharmaceutical, as suggested by Mayer.

With regards to claims 2 and 3, Sjoholm et al. discuss both transmitted and reflected radiation setups (Figure 1).

With regards to claims 5-7, Sjoholm et al. discuss detection of oxygen (page 17, column 1) while Mayer suggests that the free air in the pharmaceutical may include oxygen, carbon dioxide, or water vapor (page 2, line 58; page 4, line 43).

With regards to claim 8, Sjoholm et al. discuss monitoring the radiation as a function of time for diffusion measurements (Figure 3).

With regards to claims 9-11, Mayer suggests that level of free air within the pharmaceutical directly corresponds to the hardness, disintegration, or dissolution of the pharmaceutical (page 2, lines 48-65; page 4, line 40 – page 5, line 8).

With regards to claim 12-14, although neither Mayer nor Sjoholm et al. suggests correlating the values with flowability, aggregation properties, or density, it is obvious

that such properties would equally depend upon the concentration of free gas. The inclusion of microvoids of free gas would directly impact the structure of the pharmaceutical thereby influencing the amount of pharmaceutical than could be contained in a unit volume (i.e. density), as well as its ability to flow or aggregate. As such, one of ordinary skill in the art would have been equally motivated to correlate the free gas concentration with these solid state parameters, especially in view of the teachings of Mayer regarding the impact of free air concentrations on physical properties of a pharmaceutical.

With regards to claims 15 and 30, Mayer suggests that the pharmaceutical is a solid capsule.

With regards to claims 17-19 and 31, Sjoholm et al. suggests the use of IR radiation in the claimed range (page 17, column 1).

With regards to claims 22 and 23, Sjoholm et al. suggests a diode laser for the source and a PMT for the detector (Figure 1).

With regards to claim 29, Sjoholm et al. suggests correlation of the free gas concentration with the diffusivity of a gas in a sample (Figure 3).

With regards to claim 32, Mayer suggests that the amount of free gas can be correlated to more than one parameter (i.e. hardness and disintegrability or dissolution).

7. Claim 4 is rejected under U.S.C. 103(a) as being unpatentable over Sjoholm et al. and Mayer, as applied to claim 1 above, and further in view of Egelberg (European Patent Application # EP-0959342-A2).

The combination of Sjoholm et al. and Mayer disclose all the limitations of parent claim 1, as discussed above. However, the combination is silent with regards to measuring transmitted and reflected radiation. Sjoholm et al. only suggests measuring transmitted or reflected radiation in the alternative.

However, Egelberg teaches an IR measurement system of a pharmaceutical using either transmitted or reflected radiation (paragraphs 14-15). Egelberg further teaches that the embodiments can be combined to enable transmitted and reflected radiation measurements on a pharmaceutical (paragraph 16). Such a configuration combines the advantages of reflected measurements (i.e. improvement in position information) and the advantages of transmitted measurements (i.e. supplying information of all levels of the mixture) (paragraph 16).

Thus, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to use transmitted and reflected radiation so as to take combine the advantages of both measurement techniques, as taught by Egelberg.

8. Claim 16 is rejected under U.S.C. 103(a) as being unpatentable over Sjoholm et al. and Mayer, as applied to claim 15 above, and further in view of Faus et al. (US Patent # 6,667,802).

The combination of Sjoholm et al. and Mayer disclose all the limitations of parent claim 15, as discussed above. However, the combination is silent with regards to the solid pharmaceutical being located in a blister pack.

However, such configurations are well known in the art. For example, Faus et al. teach an NIR spectroscopy system for inspection of a pharmaceutical wherein the pharmaceutical is located in a blister pack (column 1, lines 51-66). Faus et al. teach that the NIR spectroscopy system can then be integrated with a packaging system such that the inspection and packaging steps can be combined into a single station.

Thus, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to provide the pharmaceutical in a blister pack so as to enable inspection and packaging in a single station, as taught by Faus et al.

9. Claims 20, 21, and 28 are rejected under U.S.C. 103(a) as being unpatentable over Sjoholm et al. and Mayer, as applied 1 above, and further in view of Folestad '00 (International Patent Publication # WO-00/03229-A1).

The combination of Sjoholm et al. and Mayer disclose all the limitations of parent claim 1, as discussed above. However, the combination is silent with regards to the radiation being visible or ultraviolet.

However, Folestad '00 teaches the use of a spectroscopic system for the evaluation of the quality of a pharmaceutical, which ideally employs NIR radiation. In addition, Folestad '00 teaches that the system may employ visible or UV radiation in place of IR wavelengths (page 11, lines 6-10). Thus, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to select a wavelength range in the visible or UV spectrum instead of IR, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regards to claim 28, the combination is also silent with regards to the analysis being used as feedback in a manufacturing process. Folestad '00 further teaches that the results of a NIR spectroscopic method can be used as feedback in the pharmaceutical manufacturing process (abstract). Such a configuration enables continuous and direct evaluation of the quality of the product (page 2, lines 26-30) while allowing for in-line adjustment of manufacturing parameters, thereby reducing waste (page 5, lines 20-25).

Thus, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to provide the analysis as feedback for the pharmaceutical manufacturing process, as taught by Folestad '00, so as to provide quasi-real time adjustment of manufacturing conditions for improving product quality.

10. Claim 24 is rejected under U.S.C. 103(a) as being unpatentable over Sjoholm et al. and Mayer, as applied 1 above, and further in view of Bachur et al. (US Patent Application Publication # 2003/0111607).

The combination of Sjoholm et al. and Mayer disclose all the limitations of parent claim 1, as discussed above. However, the combination is silent with regards to the use of a photodiode for the detector. Instead, Sjoholm et al. employ a PMT.

However, the use of photodiodes in the spectroscopy art are well known. For example, Bachur et al. teach a system for wavelength modulation laser spectroscopy for

detection of a gas, such as oxygen or carbon dioxide (paragraph 4). A diode laser source is applied and a detector receives the transmitted radiation to detect the gas of interest. For the detector, Bachur et al. teaches that a photodiode can be equivalently used in place of a PMT (paragraph 56).

Thus, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to provide a photodiode for the detector instead of a PMT since the photodiode and the PMT are art-recognized equivalents for detection of transmitted IR radiation in a wavelength modulation spectroscopy system, as taught by Bachur et al.

11. Claims 25-27 are rejected under U.S.C. 103(a) as being unpatentable over Sjoholm et al. and Mayer, as applied 1 above, and further in view of Folestad '02 (US Patent Application Publication # 2002/0125434).

The combination of Sjoholm et al. and Mayer disclose all the limitations of parent claim 1, as discussed above. However, the combination is silent with regards to where in the manufacturing process the analysis may occur.

Folestad '02 teaches a NIR inspection system for a pharmaceutical (abstract, paragraph 60). Folestad '02 further teaches that such a system may be integrated at various locations in a manufacturing process, including at-line, in-line, or on-line (paragraphs 38, 39, 64).

Thus, it would have been obvious for a person having ordinary skill in the art at the time the invention was made to provide the analysis at various locations in the

manufacturing process, as taught by Folestad '02, so as to provide analysis for quality control at various steps of the fabrication process.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hieftje et al. (US Patent # 4,800,279) teaches that physical properties of solid materials are able to be quantified base on infrared spectroscopy measurements.

Folestad et al. (US Patent # 6,794,670) is the corresponding US case for WO-01/22063.

Soloman (US Patent # 5,679,954) teaches the correlation of IR spectra of a pharmaceutical with its dissolution properties.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Rosenberger whose telephone number is 571-272-6107. The examiner can normally be reached on Monday - Friday with flexible hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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